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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,804

01/23/2007

Chunlin Tao

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06/04/2008

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EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

06/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,804	<b>Applicant(s)</b> TAO ET AL.	
	<b>Examiner</b> SAMANTHA SHTERENGARTS	<b>Art Unit</b> 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-72 is/are pending in the application.
- 4a) Of the above claim(s) 54,55 and 62-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-53, 56-61, and 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>17 August 2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **1 DETAILED ACTION**

### ***Priority***

1. The instant application is a national stage entry of PCT/US2004/043997, filed December 23, 2004, which claims the benefit of U.S. Provisional Application No. 60/531,955, filed December 23, 2003.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on August 17, 2006 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS document was considered. A signed copy of form 1449 is enclosed herewith.

### ***Election/Restrictions***

3. Applicant's election with traverse of Group I in the reply filed on May 22, 2007 is acknowledged. The traversal is on the ground(s) that Groups I, II, III, IV, and V, share the same special technical feature, which is the novel structure of the claimed genus. Applicant argues that just as the use of a key in a lock has unity of invention with the structure of the key, the uses of the claimed Compounds have unity of invention with the compounds themselves. . This is not found persuasive because while the compounds of Group I *may* have unity of invention with their methods of use, their special technical feature, the core, non-variable structure of the compounds, does not make a contribution over the prior art.

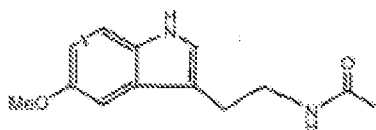
An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1).

With respect to a group of inventions claimed in an international application, unity of invention

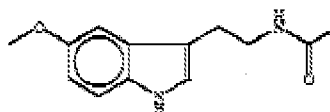
Art Unit: 1625

exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. In the instant case, the non-variable core is disclosed by the prior art in Fourtillan et al. (U.S. Patent No. 6,004,991), pages 11-12, example 2 in table. Applicant states that Fourtillan et al. discloses a different core than the provisionally elected species; however, the non-variable core is the same as in the instantly claimed genus.

Non-variable core of instantly claimed genus:



Non-variable core of prior art, Fourtillan et al.:



The core technical feature that is being claimed is taught by the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. The requirement is still deemed proper and is therefore made FINAL.

#### ***Status of Claims***

4. Claims 1-36 are cancelled. Claims 37-72 are currently pending. Claims 54-55 and 62-71 are withdrawn for being drawn to a non-elected invention. Claims 37-53 and 72 are examined on their merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 37-53, 56-61, and 72 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Garratt et al. [Garratt, Peter J, *Mapping the Melatonin Receptor. 3. Design and Synthesis of Melatonin Agonists and Antagonists Derived from 2-Phenyltryptamines*, Journal of Medicinal Chemistry, 38(7) (1995), 1132-1139.]

The instantly claimed compounds and compositions are clearly anticipated by Garratt et al. Table 1 on page 1134 exemplifies various anticipatory compounds. Instant claim 38 is anticipated by compounds 6a, 6b, and 6c. Instant claim 39 is anticipated by compound 6a. Instant claim 40 is anticipated by compound 6b. Instant claim 41 is anticipated by compound 6e. Instant claim 42 is anticipated by compound 6f. Instant claim 47 is anticipated by compounds 6a, 6b, 6c, 6e, and 6f. Instant claims 37 and 72 are clearly anticipated by compounds 6a, 6b, 6c, 6e, and 6f. Instant claims 56-59 are clearly anticipated because adding a pharmaceutically acceptable carrier, or nanoparticles (molecules of the compound) to a known compound is anticipated in the art.

Claims 37-53, 56-61, and 72 are also rejected as being clearly anticipated under 35 U.S.C. 102(b) by the following prior art references:

Art Unit: 1625

Chen, Jia Jun, *Synthesis of 2-Iodo and 2-Phenyl-[<sup>11</sup>C]melatonin: Potential PET Tracers for Melatonin Binding Sites*, *Applied Radiation and Isotopes*, 49(12) (1998), 1573-1579: Page 1577, Fig 5.

Sastre, J.A. Lopez, *Biological activity of melatonin and some analogous: geometrical and electrical requirements*, *Journal of Molecular Structure (Thermochem)* 53, (2001), 271-281: Page 274, compound 1.

Spadoni, Gilberto, *2-Substituted 5-Methoxy-N-acyltryptamines: Synthesis, Binding Affinity for the Melatonin Receptor, and Evaluation of the Biological Activity*, *Journal of Medicinal Chemistry*, 36, (1993), 4069-4074: Page 4070, compounds 4d and 4g.

Mor, Marco, *Synthesis, Pharmacological Characterization and QSAR Studies on 2-Substituted Indole Melatonin Receptor Ligands*, *Bioorganic and Medicinal Chemistry*, 9 (2001) 1045-1057: Page 1047, Table 1, compound 5j.

Ito, Satoru, *Acetone-Sensitized Photocoupling of 5-Bromouridine to Tryptophan Derivatives via Electron-Transfer Process*, *Journal of American Chemical Society*, 102 (1980) 7535-754: Page 7539, scheme 4, compound 19.

Rivara, Silvia, *Three-Dimensional Quantitative Structure—Activity Relationship Studies on Selected MT<sub>1</sub> and MT<sub>2</sub> Melatonin Receptor Ligands: Requirements for Subtype Selectivity and*

*Intrinsic Activity Modulation*, Journal of Medicinal Chemistry, 46 (2003) 1429-1439. Page 1430:  
Table 1, compound 1-10-4, 1-10-13, 1-10-17, 1-10-18, 1-10-19, 1-10-20, 1-10-21, and 1-10-22.

### ***Conclusion***

5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday, 9AM – 6PM Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang and Janet Andres can be reached on 571-272-0562 and 571-272-0867, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMANTHA SHTERENGARTS/  
Examiner, Art Unit 4131

/Janet L. Andres/  
Supervisory Patent Examiner, Art Unit 4131